K113871
1/2

# 510(K) SUMMARY
# OF SAFETY AND EFFECTIVENESS

MAR 2 5 2013

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of PRO-DENSE® Bone Graft Substitute.

| | |
|---|---|
| Submitted By: | Wright Medical Technology, Inc. |
| Date: | March 15, 2013 |
| Contact Person: | Samir Ibrahim, PhD, RAC<br>Regulatory Affairs Specialist II<br>901-290-5909<br>samir.ibrahim@wmt.com |
| Proprietary Name: | **PRO-DENSE®** Bone Graft Substitute |
| Common Name: | Bone Void Filler |
| Classification Name and Reference: | 21 CFR 888.3045 – Resorbable Calcium Salt Bone Void Filler Device – Class II |
| Device Product Code and Panel Code: | Orthopedic/87/MQV |
| Predicate Device: | K070437 – PRO-DENSE® Bone Graft Substitute |

## DEVICE INFORMATION

### A. INTENDED USE

PRO-DENSE® resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities and pelvis) to cure *in situ*. These open bone voids may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

The PRO-DENSE® paste cured *in situ* provides an open void/gap filler that can augment provisional hardware (e.g. K Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

PRO-DENSE® is provided sterile for single use only.

### B. DEVICE DESCRIPTION

PRO-DENSE® is indicated as a bone graft substitute to be injected and/or digitally packed into open bone voids/gaps that are not intrinsic to the structural stability of the skeletal system to cure *in-situ*. It is supplied in separate powder and liquid vials along with the instruments for mixing it into a paste and delivering it to the defect site. The triphasic resorption of PRO-DENSE® results in a scaffold

that is osteoconductive allowing tissue infiltration and must eventually be degraded through osteoclastic action as bone remodels within the scaffold. The clinical use of calcium sulfate, calcium phosphate, and composites thereof as a bone void filler has been well established through many peer reviewed publications.

## C. MATERIALS

PRO-DENSE® is a calcium sulfate – calcium phosphate composite bone graft substitute consisting of a powder component and an aqueous mixing solution. When the two components are mixed according to directions, an injectable paste forms and subsequently hardens via hydration reactions. The benefits of this composite include:

- Calcium Sulfate
  - Primary osteoconductive filler
  - Resorbs first primarily through simple dissolution to allow early vascular infiltration
  - Excellent clinical history
- Calcium Phosphate
  - Osteoclastic resorption
  - Secondary porous scaffold that is resorbed after primary filler
  - TCP granules are resorbed in the third and final phase

## D. SUBSTANTIAL EQUIVALENCE INFORMATION

### Technological Characteristics Comparison

The technical features of PRO-DENSE® in this submission remain identical to the predicate product cleared in K070437.

### Non-Clinical Evidence

N/A

### Clinical Evidence

A literature review was conducted to establish the safety and effectiveness of PRO-DENSE® for use in voids resulting from resected benign bone cysts/tumors in both adult and pediatric patients. This evidence was used to change the indications statement to include this patient population.

### Conclusion

The design characteristics of the subject device are identical to the predicate device and do not raise any new types of questions of safety or effectiveness. A literature search was conducted to support the addition of adult/pediatric benign bone cysts/tumor to the indications statement. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate system(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2013

Wright Medical Technology, Incorporated
% Samir Ibrahim, Ph.D., RAC
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K113871
Trade/Device Name: PRO-DENSE® Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: March 18, 2013
Received: March 19, 2013

Dear Dr. Ibrahim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number: K113871

Device Name: PRO-DENSE® Bone Graft Substitute

Indications For Use:

PRO-DENSE® resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities and pelvis) to cure *in situ*. These open bone voids may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

The PRO-DENSE® paste cured *in situ* provides an open void/gap filler that can augment provisional hardware (e.g. K Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

PRO-DENSE® is provided sterile for single use only.

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number _____

Prescription Use __√__ OR Over-The Counter Use ____
(Per21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K113871